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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/781,263 | 02/19/2004 | Yoshiyuki Inada | 087147-0450 | 3131 |
| 22428 | 7590 | 08/22/2005 | EXAMINER | |
| FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | LAMBKIN, DEBORAH C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,263

Applicant(s)

INADA ET AL.

Examiner

Deborah C. Lambkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/3/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DEBORAH C. LAMBKIN
PRIMARY EXAMINER

Status of Claims

Claims 1-10 and 11-18 are rejected for the reasons of record (except the 112 rejection under prophylaxis, indisposition and including and the recapture rejection which were overcome by amendments and arguments; all other rejections remain outstanding).

New claims 11-18 are rejected for the same reasons as those of claims 1-10 since they are directed to the same general invention.

Response to Arguments

Applicant's arguments filed 5/31/05 have been fully considered but they are not persuasive for the following reasons:

A) 2. Diuretic and Calcium Antagonist Combinations

Applicant is alleging "synergism" or "synergistic effect" as opposed to the conventional "addition" or "additive effect" of two drugs, wherein synergism cannot be extrapolated from examples but must actually be shown or demonstrated. In addition, not all combinations were shown and the publication data exhibited only indicate specific examples and is not all inclusive, hence it would cause undue experimentation to find which ones would work beyond those actually shown or contemplated by applicant.

A) 3. Angiotensin-II Mediated Diseases

The Office has recently reversed its policy on such mechanism claims. Call supervisor, Joseph McKane 571-272-0699 or myself, for further explanation if needed.

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Inserting the actual diseases contemplated by such mechanism in Markush format would cure this problem.

B) 2. "Mediated"

Applicant made conclusionary statements but failed to provide a definition for the term mediated. What does it mean? Please provide either a textbook definition or an "art" definition.

D. Applicant is applying a double standard argument which is flawed. Why is it not sufficient motivation from the teachings of Naka et al and Chakravarty et al for one of ordinary skill in the art to recognize similar benzimidazole compounds and their combination with diuretics or calcium channel blockers without an exhaustive list of specific examples yet applicant seeks to patent the same without specific exhaustive examples. The suggestion for the kind of instant combination has already been made in the art. Applicant must show unexpected results for each and every combination over the conventional addition.

Applicant should note that the claims are improperly amended.

Amendments in reissue applications must be in accordance with 37 CFR

1.173.(b).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP


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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C. Lambkin whose telephone number is 571-272-0698.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699.


DEBORAH C. LAMBKIN
PRIMARY EXAMINER
Deborah C. Lambkin
Primary Patent Examiner
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